



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0286]

Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidance assists sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products. This guidance finalizes the draft guidance issued on April 1, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. [FDA-2013-D-0286] for Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; Availability. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions – To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed

confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing

your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6483, Silver Spring, MD 20993-0002, 301-796-0970; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by CDER and CBER. For the purposes of this guidance, “formal meeting” includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference, or videoconference).

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or

interchangeable with, an FDA-licensed biological product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). The Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize a new user fee program for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the new user fee program. The performance goals, which are set forth in a letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives,¹ include meeting management goals for formal meetings that occur between FDA and sponsors or applicants during the development phase of a biosimilar biological product. This guidance describes the Agency’s current thinking on how it intends to interpret and apply certain provisions of BsUFA, and also provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products.

This guidance reflects a unified approach to all formal meetings between sponsors or applicants and FDA for biosimilar biological product development (BPD) programs. It is intended to assist sponsors and applicants in generating and submitting a meeting request and

¹ See

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf>

the associated meeting package to FDA for biosimilar biological products. This guidance does not apply to new drug or abbreviated new drug applications under section 505 of the FD&C Act or to biologics license applications under section 351(a) of the PHS Act.

FDA expects that review staff will participate in many meetings with biosimilar biological product sponsors or applicants who seek guidance relating to the development and review of biosimilar biological products. Because these meetings often will represent critical points in the regulatory process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The good meeting management practices in this guidance are intended to provide consistent procedures that will promote well-managed meetings and to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately. The following five meeting types that occur between sponsors or applicants and FDA staff during the biosimilar BPD phase are described in the guidance: (1) Biosimilar Initial Advisory meeting; (2) BPD Type 1 meeting; (3) BPD Type 2 meeting; (4) BPD Type 3 meeting; and (5) BPD Type 4 meeting.

On April 1, 2013 (78 FR 19492), FDA announced the availability of a draft version of this guidance. All comments received during the comment period for the draft guidance have been reviewed and, where appropriate, incorporated into this guidance. As a result of the public comments, information has been added to provide clarity on the process for requesting meetings, including identifying the appropriate meeting type, and the data expectations to support the appropriate meeting type.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on formal meetings between FDA and biosimilar biological product sponsors or applicants. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910-0802.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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